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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/037,182	12/21/2001	Karl Tryggvason	99,274-F	8557

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EXAMINER

CARLSON, KAREN C

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 05/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/037,182	TRYGGVASON ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Karen Cochrane Carlson, Ph.D.	1653	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 19 March 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 5-10,17 and 23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 5 is/are allowed.
- 6) ☒ Claim(s) 6-10,17 and 23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>4/24/02</u> . | 6) <input type="checkbox"/> Other: _____  |

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Applicant's election with traverse of Invention II, Claims 5-10, 17, and 23 in the paper filed March 19, 2004 is acknowledged. The traversal is on the ground(s) that the search required for the elected invention extensively overlaps with the non-elected inventions and therefore there would not be an undue burden on the Examiner to examine the non-elected inventions as well. This is not found persuasive because the elected laminin 10 is a different product than the host cells, and can be used in a variety of patentably distinct methods, all of which have different enablement and art issues.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-4, 11-16, and 18-22 have been cancelled. Claims 5-10 17, and 23 are currently pending and are under examination.

**Priority for the a5 SEQ ID NO: 2 is to SN 60/257,449 filed December 21, 2000 for the alpha chain, and SN 60/279,282 filed March 28, 2001 for laminin 10**

It is noted that high stringency conditions for hybridization are specifically defined at page 19 of the specification.

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code at page 20, line 6. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 17 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the

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invention. Claim 17 is worded awkwardly when the phrase "laminin 10 according to a method" is used. It appears that what is meant is "laminin 10 produced by a method".

The following Table shows the % identity between the sequences set forth in the claims and those found for Mouse and for Human sequences

<u>SEQ ID NO</u>	<u>% identity to Mouse</u>	<u>% identity to Human</u>
$\alpha$ 5 2	78.7	99.9
$\alpha$ 5 4	100	79.7
$\beta$ 1 6	100	93.7
$\beta$ 1 8	100	93.2
$\beta$ 1 10	100	93.7
$\beta$ 1 12	100	94.1
$\gamma$ 1 14	93.7	100
$\gamma$ 1 16	94.3	100
$\gamma$ 1 18	99.2	93.7
$\gamma$ 1 20	99.2	94.2

A search of the sequences against the following references were used to provide the information in the Table above:

Miner et al. (1995. J. Biol. Chem. 270:28523-28526) for SEQ ID NOs: 2 & 4.

Durkin et al. (1997. FEBS Lett 411: 296-300) for SEQ ID NOs: 2 & 4.

Sasaki et al. (1987. P.N.A.S. 84: 935-939) for SEQ ID NOs: 6, 8, 10, & 12.

Pikkarainen et al. (1987.J. Biol. Chem 262:10454-10462) for SEQ ID NOs: 6, 8, 10, & 12.

Sasaki et al. (1987. J. Biol. Chem 262: 17111-17117) for SEQ ID NOs: 14, 16, 18, & 20.

Pikkarainen et al. (1988.J. Biol. Chem 263:6751-6758) for SEQ ID NOs: 14, 16, 18, & 20.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 6-10, 17, and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Miner et al. (1997; J. Cell Biol. 137(3): 685-701). Miner et al. teach isolated mouse laminin 10 hetero-trimers comprising  $\alpha 5$  chain,  $\beta 1$  chain, and  $\gamma 1$  chain (see Fig. 10B and page 700, left col. para. 1; Claim 6). Because laminin 10 isolated from natural sources does not differ from recombinantly produced laminin 10, Claim 7 is included in this rejection. Claim 10 is anticipated because the limitation "R3" is met, as is "R3e" because the laminin 10 was isolated via antibody. Given the high identity across species of laminin chains (as evidenced in Miner et al. by rat antibody recognizing mouse laminin 10 and by the Table set forth above), one skilled in the art would surmise that the chains found in the mouse laminin 10 of Miner et al. would have at least 70% identity to the sequences set forth in Claim 9 and 17, and/or be encoded by polynucleotides that would hybridize to the sequences of Claim 8. Indeed, at page 30, line 16 of the specification, SEQ ID NO: 3 depicts cDNA encoding mouse  $\alpha 5$ . Pharmaceutical compositions of laminin 10 is found at page 687, col. 1, para. 4 (Claim 23).

Claim 5 is allowable.

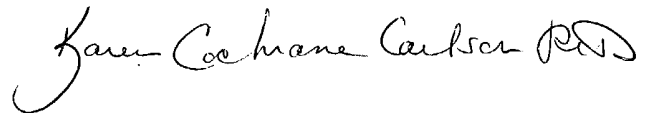
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Cochrane Carlson, Ph.D. whose telephone number is 571-272-0946. The examiner can normally be reached on 7:00 AM - 4:00 PM, off alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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A handwritten signature in black ink that reads "Karen Cochrane Carlson Ph.D." The signature is written in a cursive, flowing style.

**KAREN COCHRANE CARLSON, PH.D**  
**PRIMARY EXAMINER**